

**Section II. (Remarks)****Cancellation of Claims 59-82**

Consistent with the election of Group I claims 1-58 in the December 29, 2003 Response, Applicants hereby cancel non-elected claims 59-82, with express reservation of rights for filing one or more divisional patent applications for subject matter recited in such cancelled claims during the pendency of the present application or divisions thereof.

**Amendment of Claim 17**

Claim 17 has been hereby amended to correct the informality as indicated on page 2, second paragraph of the March 15, 2004 Office Action.

**Response to the Obviousness-Type Double Patenting Rejection**

In the March 15, 2004 Office Action, the Examiner rejected claims 1-58 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 6,139,746 (hereinafter "the '746 Patent").

Applicants respectfully traverse.

Amended claim 1, from which claims 2-58 depend, expressly requires:

"1. A method for sequentially separating components of milk, comprising the steps of:

(a) providing a milk source;

(b) **effectuating a sufficient flow of milk from the milk source through one or more cross-flow filtration modules**, using one or more fluid delivery means, wherein each fluid delivery means is connected to at least one cross-flow filtration module; and

(c) sequentially capturing one or more filtration fractions generated by the cross-flow filtration modules,

**wherein the milk is physically separated by said one or more cross-flow filtration modules into milk components, and wherein said**

**physical separation of milk components is based on their different molecular weights and/or operating conditions.”**

The instant specification as originally filed states on page 10 that “[t]he present invention uses cross-flow filtration to physically separate and isolate the above listed components of milk, based on their different molecular weights and surface chemistry, and thus avoiding introducing any unnatural chemical additives into the milk products.”

Further, the specification states on page 20, second and third paragraphs that various operating conditions such as pressure and temperature are critical for optimizing the separation results.

It is therefore clear that Applicant’s claimed invention as recited by claim 1 of the present application requires:

- (1) flow of milk through cross-flow filtration modules; and
- (2) physical separation of milk components by cross-flow filtration modules according to their different molecular weights and/or operating conditions.

In contrast, claim 1 of the ‘746 Patent, which is representative of claims 1-62 thereof, recites:

1. A process for purifying one or more target substances from a source liquid, said process comprising:

contacting the source liquid with a chromatography resin;

incubating the source liquid with the chromatography resin for a sufficient contact time to allow the resin to bind a desired fraction of one or more target substances,

recirculating the chromatography resin in a cross-flow filter wherein the following steps are performed:

concentrating the chromatography resin and separating contaminants from the chromatography-resin-bound target substance by concentration and/or diafiltration;

eluting the target substance from the chromatography resin; and

separating the target substance from the chromatography resin by diafiltration;

recovering the target; and

optionally concentrating the target substance.”

Such claim 1 of the ‘746 Patent requires initial contact of the source liquid with a chromatography resin to effect binding of the target substance with the chromatography resin, and the chromatography resin, instead of the source liquid, is subsequently passed through the cross-flow filter.

**Nothing in such claim 1 of the ‘746 Patent provides any derivative basis for a process in which the source liquid, such as milk, is flowed through the cross-flow filter, as required by claims 1-58 of the present application.**

Further, claim 1 of the ‘746 Patent discloses a process in which the target substances are separated from the source liquid based on their binding affinity to the chromatography resin.

**Nothing in such claim 1 of the ‘746 Patent provides any derivative basis for separating target substances from a source liquid such as milk based on their different molecular weights and/or operating conditions, as required by claims 1-58 of the present application.**

Therefore, the claimed subject matter of claim 1 of the present application is patentably distinguished over claim 1 of the ‘746 Patent, and Applicants hereby request the Examiner to reconsider, and upon reconsideration to withdraw, the obviousness-type double patenting rejection of claims 1-58 of the present application.

#### **Response to the 102(e) and 103(a) Rejection**

In the March 15, 2004 Office Action, the Examiner rejected claims 1-58 under either 35 U.S.C. 102(e) or 35 U.S.C. 103(a) as being unpatentable over Kopf U.S. Patent No. 6,139,746 (hereinafter “Kopf”).

Specifically, the Examiner asserted that Kopf teaches a method for separating components of milk comprising providing a milk source, filtering the milk using cross-flow filtration, and sequentially capturing the filtration fractions.

Applicants respectfully disagree, for the following reasons.

As mentioned hereinabove, Applicant's claimed invention as recited by claim 1 of the present application (from which claims 2-58 depend) requires:

- (1) flow of milk through cross-flow filtration modules; and
- (2) physical separation of milk components by cross-flow filtration modules according to their different molecular weights and/or operating conditions.

Like the '746 Patent, Kopf discloses a process for purifying target substances from a source liquid (such as milk, colostrums, cheese whey, etc.) by first contacting the source liquid with a chromatography resin, wherein such chromatography resin is then recirculated through a cross-flow filter system (see Kopf, column 3, lines 36-67; column 4, lines 1-2).

**Nothing in Kopf teaches or suggests that the source liquid, such as milk, can be flowed through the cross-flow filter, as required by claims 1-58 of the present application.**

More importantly, Kopf teaches that milk proteins can be "separated sequentially from whey by use of a series of specific chromatography resins, each linked with ligands that bond targeted proteins," and such ligands "can be ion exchangers, immunoglobulins, native proteins, or any affinity ligands that bind selectively or preferentially to the target proteins and can be linked to the resins" (see Kopf, column 16, lines 26-35).

**It is clear that the milk separation process disclosed by Kopf separates the milk source liquid into various milk components based on their different binding affinities to the chromatography resins, not their molecular weights and/or operating conditions, as expressly required by claims 1-58 of the present application.**

Therefore, Applicants' claimed invention as recited by claims 1-58 of the present application patentably distinguishes over the Kopf reference.

### **CONCLUSION**

Based on the foregoing, pending claims 1-58 as cancelled/amended herein are in form and condition for allowance. Favorable action therefore is requested.

No fee is rendered payable in association with this Amendment. Nevertheless, the Office is hereby authorized to charge any fee that is necessary for the entry of this Amendment to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

If any issues remain outstanding in this application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350.

Respectfully submitted,



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